Motorized arm support augmenting upper extremity function of people with Duchenne Muscular Dystrophy

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Ethical review	Approved WMO
Status	Pending
Health condition type	Musculoskeletal and connective tissue disorders congenital
Study type	Interventional

Summary

ID

NL-OMON53514

Source
ToetsingOnline

Brief title
Motorized arm support for DMD

Condition

- Musculoskeletal and connective tissue disorders congenital
- Muscle disorders

Synonym
DMD, Duchenne muscular dystrophy

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: NWO TTW

Intervention

Keyword: Duchenne Muscular Dystrophy, exoskeleton, orthosis, upper extremity

Outcome measures

Primary outcome

Sub-study 1) • Torque-angle values

Sub-study 2) Comparison of the three different compensation strategies:

• Surface electromyography (sEMG) amplitude

• Joint angles (according to SEA)

• Residual interaction forces (according to the force sensor on interface sleeve)

Sub-study 3) Feasibility and usability of the arm support vs. no arm support:

• Surface electromyography (sEMG) amplitude

• Performance of the Upper Limb (PUL)

• Reachable workspace with Vicon upper limb model

• Fatigue (sEMG with respect to maximal measured value in no arm support condition and RPE)

• Usability (SUS and self-developed questionnaire)

Secondary outcome

Sub-study 1)

• Maximal passive ROM (limit)

• Maximal torque in end movement (limit)

Sub-study 2)

• Fatigue (RPE)

• Perceived workload (NASA Task-Load-Index)

Sub-study 3)

• Design requirements of the motorized arm support

Study description

Background summary

Duchenne muscular dystrophy (DMD) is a progressive X-linked disorder characterized by progressive muscle wasting and weakness, resulting in loss of functional abilities. Until now no cure is found but the life expectancy is increased from around 14 years to over 35 years. Therefore, the lifespan wherein patients with DMD need support of their upper extremity to stay more independent in activities of daily living (ADL) becomes longer and more important to improve their quality of life. In a more impaired phase, these patients can benefit from a motorized arm support to assist in ADL. Because there is a low percentage active exoskeleton of all commercial available exoskeletons, a new motorized arm support is developed which we want to test in a small DMD population.

Study objective

The primary objectives of the different substudies are:
1) to identify the level and behavior of passive forces in the arm
2) compare different weight and joint impedance compensation strategies of the motorized arm support
3) evaluate the overall performance (feasibility and usability) of the developed prototype in boys and men with DMD.

Study design

This is an explorative pilot study

Intervention

A prototype of a motorized arm support is developed. It can move the right arm of the participant in four degrees of freedom (three in shoulder, one in elbow) by Series Elastic Actuators. The arm support is attached to a support frame, which can be placed around participants. It is not yet applicable in daily life, but tested in an investigational, controlled setting.

Study burden and risks

The risks associated to the use of the arm support are minimalised (see extensive risk-analysis which is performed) and the tasks that we ask the participants to perform are movements they make in daily life and have therefore no extra burden. Because the study is split in different parts, the amount of time participation takes (4 visits taking between 2 and 4 hours) can be seen as a burden. However, the benefits of the steps that can be taken in the development of a motorized arm support are high.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (16-17 years)
Adults (18-64 years)

Inclusion criteria

DNA established diagnosis of DMD
Brooke scale 4
Age >= 16 years

Able to grab objects
Able to sit stable upright without arm support
Body dimensions are compatible with the device (e.g. forearm circumference smaller than 31 cm; upper arm length between 23.5 and 33.5 cm)
Sufficient language skills and normal cognition

Exclusion criteria

Injury of the right upper extremity
Active electrical implants (e.g. pacemaker, cochlear implant)
Epilepsy
Wheelchair height at shoulder location above shoulder that cannot be tilted posterior.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	30-11-2023
Enrollment:	5
Type:	Anticipated

Medical products/devices used

Generic name:	DAROR - Duchenne ARm ORthosis
Registration:	No

Ethics review

Approved WMO Date:	10-11-2023
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL79738.000.23